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EXAMINER	
GAMI, TEJAL	

ART UNIT	PAPER NUMBER
2121	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/517,381	KANEKO ET AL.	
	Examiner	Art Unit	
	TEJAL J. GAMI	2121	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6 and 9-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6 and 9-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This office action is responsive to a REQUEST FOR CONTINUED EXAMINATION entered April 28, 2009 for the patent application 10/517381.

Status of Claims

2. Claims 6 and 9-13 were rejected in the last Office Action dated October 29, 2008.

As a response to the October 29, 2008 office action, Applicant has Amended claims 6, 9, 10, and 13.

Claims 6 and 9-13 are now presented for examination in this office action.

Claim Rejections - 35 USC § 101

3. Examiner thanks applicant for amending the claims in response to the U.S.C. 101 rejection presented in the previous office action. The U.S.C. 101 rejection has been withdrawn.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 6 and 9-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 6, 9, 10, and 13 recite the phrase "it is difficult to estimate". It is not clear how the difficulty is determined, and how/when it is considered as "difficult." The term "difficult" is a relative term which render the claims indefinite. The phrase "it is difficult to estimate" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Objections

6. Claim 13 is objected to because of the following informalities:

A semicolon appears to be missing at the end of Line 8.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 6 and 9-13 is rejected under 35 U.S.C. 102(e) as being anticipated by Norris et al. (WO 01/65441).

As to independent claim 6, Norris discloses a medicine prototype support system for an ingredient manufacturer (e.g., suppliers) (see Page 11, Lines 25-28) developing medical product (e.g., pharmaceutical) (see Page 5, Lines 4-6) at a request of a product manufacturer (e.g., affiliates) (see Page 5, Lines 22-24) comprising:

one or more computer processors (e.g., computers) (see Page 10, Network Environment; and Figure 1);

a database using a storage device for storing main ingredient information (e.g., stored in the system database) (see Page 5, Lines 25-29) comprising at least confidential first main ingredient information (e.g., main ingredient) (see Page 8, Line 14) and second main ingredient information (e.g., formulation database to generate formulations and supply options that contain components) (see Page 9, Lines 6-8; and Figure 17), the first confidential main ingredient information being confidential information (e.g., privately maintained formulation data) (see Page 11, Lines 25-28) of the product manufacturer (e.g., affiliates) (see Page 5, Lines 22-24);

communication means (e.g., server) for receiving main ingredient information from the data base (e.g., formulation data) (see Page 11, Lines 25-28);

information conversion means using at least one of the one or more computer processors (e.g., computers) (see Page 10, Network Environment; and Figure 1) for selecting a second main ingredient information that has one or more material properties similar (e.g., interchangeable) (see Page 19, Lines 1-4) to the confidential (e.g., privately maintained formulation data) (see Page 11, Lines 25-28) first main ingredient information (see Figure 8 for "a flow diagram of a general process for a user to sort

through a formulation database to select a set of matching formulations) and from which it is difficult to estimate one or more medically effective ingredients of the confidential first main ingredient information (e.g., limits and prioritizes features in selecting the formulation; end use; product characteristics; interchangeable) (see Page 16, Lines 6-11, 28-31; Page 17, Lines 8-11; Page 18, Lines 13-20; Page 19, Lines 1-4);

composition ingredient determination means using at least one of the one or more computer processors for selecting composition ingredient information based on the first main ingredient information and the selected second main ingredient information (e.g., formulation ingredient components) (see Page 8, Line 8 to Page 9, Line 11); and

communication means (e.g., server) for transmitting the selected second main ingredient information (e.g., formulation) and the selected composition ingredient information (e.g., components) to a computer system of a composition manufacturer (e.g., customer for assembly) (see Page 13, Lines 25-28), wherein the medicine prototype support system is configured to receive a first request for prototype manufacture (e.g., formulations), including the confidential first main ingredient information (e.g., privately maintained formulation data) (see Page 11, Lines 25-28), from a computer system of the product manufacturer (e.g., affiliates) (see Page 5, Lines 22-24), to select the second main ingredient information using the information conversion means (e.g., comparison) (see Figure 8 for "a flow diagram of a general process for a user to sort through a formulation database to select a set of matching formulations), to select the composition ingredient information using the composition

ingredient determination means (e.g., formulation ingredient components) (see Page 8, Line 8 to Page 9, Line 11), and to transmit a second request for prototype manufacture including the selected second main ingredient information (e.g., formulation) and the selected composition ingredient information (e.g., components) to a computer system of the composition manufacturer (e.g., customer for assembly) (see Page 13, Lines 25-28), so that the confidential first main ingredient information (e.g., granted access to formulations the affiliates decide to make available to them) received from the computer system of the product manufacturer (e.g., affiliates) (see Page 5, Lines 22-24) is not transmitted to the computer system (e.g., privately maintained formulation data) (see Page 11, Lines 25-28) of the composition manufacturer (e.g., customer) (see Page 5, Lines 18-24).

As to independent claim 9, Norris discloses a medicine prototype support system for an ingredient manufacturer (e.g., suppliers) (see Page 11, Lines 25-28) developing medical product (e.g., pharmaceutical) (see Page 5, Lines 4-6) at a request of a product manufacturer (e.g., affiliates) (see Page 5, Lines 22-24) comprising:

one or more computer processors (e.g., computers) (see Page 10, Network Environment; and Figure 1);

a database using a storage device for storing main ingredient information (e.g., stored in the system database) (see Page 5, Lines 25-29) comprising at least confidential first main ingredient information (e.g., main ingredient) (see Page 8, Line 14) and second main ingredient information (e.g., formulation database to generate formulations and supply options that contain components) (see Page 9, Lines 6-8; and

Figure 17), the first confidential main ingredient information being confidential information (e.g., privately maintained formulation data) (see Page 11, Lines 25-28) of the product manufacturer (e.g., affiliates) (see Page 5, Lines 22-24) and the second main ingredient information being non-confidential (e.g., granted access to formulations the affiliates decide to make available to them) (see Page 5, Lines 22-24);

information conversion software (e.g., computers) (see Page 10, Network Environment; and Figure 1) that selects a second main ingredient information having one or more properties similar (e.g., interchangeable) (see Page 19, Lines 1-4) to a confidential (e.g., privately maintained formulation data) (see Page 11, Lines 25-28) first main ingredient information (see Figure 8 for "a flow diagram of a general process for a user to sort through a formulation database to select a set of matching formulations) and from which it is difficult to estimate one or more medically effective ingredients of the confidential first main ingredient information (e.g., limits and prioritizes features in selecting the formulation; end use; product characteristics; interchangeable) (see Page 16, Lines 6-11, 28-31; Page 17, Lines 8-11; Page 18, Lines 13-20; Page 19, Lines 1-4);

composition ingredient determination software that selects a composition ingredient information based on one or more properties of the confidential first main ingredient information and selected second main ingredient information (e.g., formulation ingredient components) (see Page 8, Line 8 to Page 9, Line 11); and

a server (e.g., server) for transmitting the selected second main ingredient information (e.g., formulation) and the selected composition ingredient information (e.g., components) to a computer system of a composition manufacturer (e.g., customer for

assembly) (see Page 13, Lines 25-28), wherein the medicine prototype support system is configured to receive a first request for prototype manufacture (e.g., formulations), including the confidential first main ingredient information (e.g., privately maintained formulation data) (see Page 11, Lines 25-28), from the product manufacturer (e.g., affiliates) (see Page 5, Lines 22-24), to select the second main ingredient using the information conversion software (e.g., comparison) (see Figure 8 for "a flow diagram of a general process for a user to sort through a formulation database to select a set of matching formulations), to select the composition ingredient using the composition ingredient determination software (e.g., formulation ingredient components) (see Page 8, Line 8 to Page 9, Line 11), and to transmit a second request for prototype manufacture including the second main ingredient information (e.g., formulation) and the composition ingredient information (e.g., components) to the composition manufacturer system (e.g., customer for assembly) (see Page 13, Lines 25-28), so that the confidential first main ingredient information (e.g., granted access to formulations the affiliates decide to make available to them) received from the computer system of the product manufacturer (e.g., affiliates) (see Page 5, Lines 22-24) is not transmitted to the computer system (e.g., privately maintained formulation data) (see Page 11, Lines 25-28) of the composition manufacturer (e.g., customer) (see Page 5, Lines 18-24).

As to independent claim 10, Norris discloses a method of using a medicine prototype support system (e.g., pharmaceutical) (see Page 5, Lines 4-6) comprising the steps of:

receiving a first request for prototype manufacture (e.g., manufacture of pharmaceuticals) (see Page 5, Lines 4-6) from a computer system of a product manufacturer (e.g., affiliate) (see Page 5, Lines 22-24) via a communications server (e.g., computers) (see Page 10, Network Environment; and Figure 1), the request including main ingredient information (e.g., main ingredient) (see Page 8, Line 14) that is confidential information (e.g., privately maintained formulation data) (see Page 11, Lines 25-28) of the product manufacturer (e.g., affiliates) (see Page 5, Lines 22-24);

storing (e.g., stored in the system database) the confidential first main ingredient information in a database contained in a storage device (see Page 5, Lines 25-29);

using the database (e.g., computers) (see Page 10, Network Environment; and Figure 1) to select a second main ingredient having one or more properties similar (e.g., interchangeable) (see Page 19, Lines 1-4) to the confidential (e.g., privately maintained formulation data) (see Page 11, Lines 25-28) main ingredient (see Figure 8 for "a flow diagram of a general process for a user to sort through a formulation database to select a set of matching formulations) and from which it is difficult to estimate one or more medically effective ingredients of the confidential first ingredient information (e.g., limits and prioritizes features in selecting the formulation; end use; product characteristics; interchangeable) (see Page 16, Lines 6-11, 28-31; Page 17, Lines 8-11; Page 18, Lines 13-20; Page 19, Lines 1-4);

determining a composition ingredient based on the confidential main ingredient information and the selected second main ingredient information (e.g., formulation ingredient components) (see Page 8, Line 8 to Page 9, Line 11);

transmitting a second request for prototype manufacture (e.g., formulation components) to a computer system of a composition manufacturer (e.g., customer for assembly) via the communications server (e.g., server) (see Page 13, Lines 25-28), the request for prototype manufacture including the identities of the selected second main ingredient (e.g., comparison) (see Figure 8 for "a flow diagram of a general process for a user to sort through a formulation database to select a set of matching formulations) and the selected composition ingredient (e.g., formulation ingredient components) (see Page 8, Line 8 to Page 9, Line 11); and

maintaining the confidentiality of the confidential first main ingredient information (e.g., granted access to formulations the affiliates decide to make available to them) (see Page 5, Lines 22-24) by not transmitting the confidential first main ingredient information to the computer system (e.g., privately maintained formulation data) (see Page 11, Lines 25-28) of the composition manufacturer (e.g., customer) (see Page 5, Lines 18-24).

As to independent claim 13, Norris discloses a medicine prototype support system for an ingredient manufacturer (e.g., suppliers) (see Page 11, Lines 25-28) developing medical product (e.g., pharmaceutical) (see Page 5, Lines 4-6) at a request of a product manufacturer (e.g., affiliates) (see Page 5, Lines 22-24) comprising:

one or more computer processors (e.g., computers) (see Page 10, Network Environment; and Figure 1);

a database using a storage device for storing main ingredient information (e.g., stored in the system database) (see Page 5, Lines 25-29) comprising at least

confidential first main ingredient information (e.g., main ingredient) (see Page 8, Line 14) and second main ingredient information (e.g., formulation database to generate formulations and supply options that contain components) (see Page 9, Lines 6-8; and Figure 17), the confidential first main ingredient information being confidential information (e.g., privately maintained formulation data) (see Page 11, Lines 25-28) of the product manufacturer (e.g., affiliates) (see Page 5, Lines 22-24);

information conversion means using at least one of the computer processors (e.g., computers) (see Page 10, Network Environment; and Figure 1) for selecting a second main ingredient information by comparing (e.g., comparison 809) (see Figure 8) properties of a confidential main ingredient information stored in the database (e.g., privately maintained formulation data) (see Page 11, Last Line of Second Paragraph) with properties of a plurality of potential second main ingredients stored in the database (see Figure 8 for "a flow diagram of a general process for a user to sort through a formulation database to select a set of matching formulations);

composition ingredient determination means for selecting a composition ingredient based on one or more properties of the confidential first main ingredient information and selected second main ingredient information (e.g., formulation ingredient components) (see Page 8, Line 8 to Page 9, Line 11); and

communication means (e.g., server) (see Page 13, Lines 25-28) for receiving confidential first main ingredient information (e.g., privately maintained formulation data) (see Page 11, Lines 25-28) from a product manufacturer (e.g., affiliates) (see Page 5, Lines 22-24) and for transmitting the selected second main ingredient information (e.g.,

formulation) and the selected composition ingredient information (e.g., components) to a composition manufacturer system (e.g., customer for assembly) (see Page 13, Lines 25-28), wherein the medicine prototype support system is configured to receive a request for prototype manufacture (e.g., formulations) including the confidential first main ingredient information (e.g., privately maintained formulation data) (see Page 11, Lines 25-28) from the product manufacturer (e.g., affiliates) (see Page 5, Lines 22-24), to select the second main ingredient using the information conversion means (e.g., comparison) (see Figure 8 for "a flow diagram of a general process for a user to sort through a formulation database to select a set of matching formulations), to select the composition ingredient using the composition ingredient determination means (e.g., formulation ingredient components) (see Page 8, Line 8 to Page 9, Line 11), and to transmit a second request for prototype manufacture including the second main ingredient information (e.g., formulation) and the composition ingredient information (e.g., components) to the composition manufacturer system (e.g., customer for assembly) (see Page 13, Lines 25-28), the medicine prototype support system does not reveal the identity of the confidential first main ingredient (e.g., privately maintained formulation data) (see Page 11, Lines 25-28) to the composition manufacturer system (e.g., customer) (see Page 5, Lines 18-24), and the information conversion means (e.g., computers) (see Page 10, Network Environment; and Figure 1) selects the second main ingredient such that it is difficult to estimate one or more medically effective ingredients of the confidential first main ingredient information from the selected second main ingredient information (e.g., limits and prioritizes features in selecting the formulation;

end use; product characteristics; interchangeable) (see Page 16, Lines 6-11, 28-31; Page 17, Lines 8-11; Page 18, Lines 13-20; Page 19, Lines 1-4).

As to dependent claim 11, Norris teaches the method of claim 10, further comprising transmitting a second request for prototype manufacture to a second composition manufacturer (see Page 7, Lines 10-17).

As to dependent claim 12, Norris teaches the method of claim 10, wherein the confidential main ingredient information (e.g., privately maintained formulation data) (see Page 11, Lines 25-28) received from the product manufacturer (e.g., affiliates) (see Page 5, Lines 22-24) includes the identity of the main ingredient (e.g., formulation ingredient components) (see Page 8, Line 8 to Page 9, Line 11; and Figure 17).

Response to Arguments

9. Applicant's amendment and arguments filed April 28, 2009 have been fully considered. The amendment does not overcome the original art rejection and the arguments are not persuasive. The following are the Examiner's observations in regard thereto.

Applicant Argues:

Norris Does Not Select a Second Main Ingredient from a First Main Ingredient.

Examiner Responds:

Examiner is not persuaded. See office action above, particularly see Figure 17 and Page 8, Line 8 to Page 9, Line 11 for formulation ingredient components using a formulation database to generate formulations and supply options that contain

components. Under such considerations, the prior art anticipates selecting a second main ingredient from a first main ingredient.

Applicant Argues:

Norris Teaches Only One Customer.
Norris, therefore, teaches the presentation of formulations to a customer in response to "performance criteria" received from that same customer. Accordingly, Norris does not teach receiving "a request for prototype manufacture ... from the product manufacturer" and transmitting "a second request for prototype manufacture ... to the composition manufacturer system," as recited in claims 6, 9, and 13. Instead of receiving a first request for manufacture from a first manufacturer (the product manufacturer) and transmitting a second request for manufacture to a second manufacturer (the composition manufacturer), Norris receives a set of requirements from a first customer and transmits proposed formulations to that same customer.

Examiner Responds:

Examiner is not persuaded. The prior art teaches "a request for prototype manufacture from the product manufacturer (e.g., affiliates) (see Page 5, Lines 18-24)" and transmitting "a second request for prototype manufacture to the composition manufacturer system (e.g., customer for assembly) (see Page 13, Lines 25-28)." Under such considerations, the prior art teaches a product manufacturer (e.g., affiliates) and composition manufacturer (e.g., customer).

Applicant Argues:

Norris Does Not Select Composition Ingredients Based on Properties of the First and Second Main Ingredients.

Examiner Responds:

Examiner is not persuaded. See office action above, particularly see Figure 17 and Page 8, Line 8 to Page 9, Line 11 for formulation ingredient components using a formulation database to generate formulations and supply options that contain

components. Under such considerations, the prior art anticipates selecting composition ingredients based on properties of the first and second main ingredients.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tejal J. Gami whose telephone number is (571) 270-1035. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Albert DeCady can be reached on (571) 272-3819. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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